# In the United States Court of Federal Claims

**OFFICE OF SPECIAL MASTERS**

**No. 15-612V**

(to be published)

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| ALAYNA MCDONALD, | * | |
| | * | Chief Special Master Corcoran |
| Petitioner, | * | |
| | * | Filed: February 3, 2023 |
| v. | * | |
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| SECRETARY OF HEALTH AND HUMAN SERVICES, | * | |
| | * | |
| Respondent. | * | |
| | * | |

*Phyllis Widman*, Widman Law Firm, LLC, Northfield, NJ, for Petitioner.

*Mallori Openchowski*, U.S. Department of Justice, Washington, DC, for Respondent.

## ENTITLEMENT DECISION[1]

On June 16, 2015, Craig and Mary Beth McDonald, on behalf of their then-minor daughter, Alayna, filed a petition seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program").[2] Their Petition alleged that Ms. McDonald suffered from mitochondrial and methylation/glutathione dysfunction causing or exacerbating chronic fatigue after receipt of several doses of the human papillomavirus ("HPV") vaccine (marketed under the tradename "Gardasil") in 2012. Petition (ECF No. 1) at 1. Ms. McDonald became the proper

[1] Because this Decision contains a reasoned explanation for my actions in this case, it must be posted on the United States Court of Federal Claims website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public. *Id*.

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) ("Vaccine Act" or "the Act"). Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

Petitioner once she turned 18, and the caption was accordingly amended. ECF No. 76. Petitioner's theory has also shifted to one alleging that the HPV vaccine doses she received caused a toxic reaction, due to undisclosed vaccine ingredients.

After a years-long litigation course featuring a collective total of *sixteen* written expert reports (not counting several produced by experts whose opinions have since been abandoned), the matter is ready for resolution via ruling on the record—and to that end the parties have briefed their positions. Petitioner's Brief in Support, dated January 14, 2022 (ECF No. 135) ("Br."); Respondent's Opposition, dated May 20, 2022 (ECF No. 141) ("Opp."); Petitioner's Reply, dated June 10, 2022 (ECF No. 144) ("Reply"). For the reasons set forth below, however, I do not find in Petitioner's favor. Neither causation theory advanced—that unidentified silicone-based components of the vaccine, or its adjuvants, can cause chronic fatigue and associated symptoms—was established with sufficient reliable scientific or medical proof.

## I. Factual Background

Ms. McDonald was born on April 9, 1998, and was fourteen years-old when she received the HPV vaccine doses at issue (now more than ten years ago). Ex. 1 at 1. Her medical history is significant for hypertrophy of her lower limb, exercise-induced asthma, allergic rhinitis, and migraine headaches. Ex. 9 at 6.

On June 14, 2012, Petitioner visited her primary care physician, Wendy Wallace, D.O., for a well-child check. Ex. 3 at 13–15. At this time, her sleep habits were deemed normal. *Id.* at 14. In addition, she was physically active, experiencing only some conditions consistent with her prior medical history (*e.g.*, hemihypertrophy of lower limb, and calf and knee pain). *Id.* Petitioner received the first HPV vaccine dose at this visit, with the second two months later (on August 17, 2012), and the third at the end of the year (on December 26, 2012). *Id*. at 15, 25.

Importantly, the medical records themselves (from the time period between the administration of the first HPV dose in June 2012 to her last over six months later) document *no* evidence of any post-vaccination reaction, or symptoms consistent with what is alleged in this case. *See generally* Ex. 3 at 13–14 (no mention of fatigue at doctor's visits from June to December 2012). Petitioner (and her parents, who originally brought the claim on her behalf), however, maintains that she began experiencing fatigue-like symptoms the summer of 2012, with her sleepiness more evident as the fall progressed. *See, e.g.*, Affidavit of Mary Beth McDonald, dated January 11, 2016, filed as Ex. 22 (ECF No. 19-2) at 2.

The first actual medical record setting forth any allegedly vaccine-related symptom is from 2013. On January 31, 2013, Ms. McDonald went to Wendy Wallace, D.O., reporting that she had been experiencing daily mood changes beginning three to four weeks before (or around the

beginning of January) which she did not associate with her menses, plus trouble falling asleep, and waking up fatigued and unrefreshed. Ex. 3 at 12. Dr. Wallace assessed her with "mood changes," and ordered testing, although Petitioner also agreed to pursue counseling as well as a potential psychiatric evaluation. *Id*. at 13. It appears from the record an initial evaluation was sought in mid-February 2013 at Associates of Springfield Psychology on February 14, 2013, with the intake form indicating "anxiety disorder." Ex 19 at 1. However, treatment there appears to have ceased as of March 12, 2015, and no records detailing the scope or findings associated with that treatment were disclosed or filed in this case (likely due to the provider's privacy concerns).

Petitioner thereafter returned to Dr. Wallace on March 13, 2013, complaining of general fatigue and performance issues in school. Ex. 3 at 11. Laboratory test results were positive for a Lyme antibody and some other antibodies. Ex. 14 at 44–47. However, Dr. Wallace nevertheless diagnosed Ms. McDonald with infectious mononucleosis plus "other malaise and fatigue." Ex. 13 at 22. Dr. Wallace also at this time wrote a letter, addressed "To Whom It May Concern," stating that treaters were following Petitioner for mononucleosis with extreme fatigue, and that she might require rest during the day. *Id.* She prepared a second letter almost two weeks later (dated March 21, 2013) stating that Petitioner was also being followed for Lyme disease, and that her conditions were associated with extreme fatigue. *Id.* at 20.

The next month, Petitioner saw Dr. Wallace again (on April 19, 2013), continuing to complain of intermittent fatigue plus concentration issues interfering with her schoolwork. Ex. 3 at 9–11. Laboratory tests to check her thyroid functioning were ordered but generated negative results. Ex. 14 at 63–73. Dr. Wallace proposed that Ms. McDonald undergo a sleep study along with a Lyme disease consultation. Ex. 3 at 10. Petitioner also had a urology evaluation that May, at which time she now identified November 2012 (or before the third HPV dose, but nearly three months after the second dose) as onset of her "ongoing health issues"—contrary to earlier records. Ex. 5 at 18. She reported no history of urinary tract infections or low grade fevers, but underwent an ultrasound due to her pain complaints. *Id.*

Ms. McDonald also saw an infectious disease specialist, Michael Sebert, M.D., in June 2013, at which time she reported persistent fatigue since December 2012. Ex. 18 at 5. Dr. Sebert, however, opined that her Lyme disease test result had been a false-positive, recommended against repeat testing given her inconsistent clinical presentation, and otherwise found nothing supportive of an infectious explanation for her symptoms. *Id*. at 6–7. Later in June she returned to Dr. Wallace, now with no symptoms complaints plus reports of good/normal sleep (other than an occasional nap). Ex. 3 at 7–8.

For the remainder of 2013, Petitioner sought treatment for her generalized fatigue plus some new symptoms. On July 8, 2013, for example, she saw neurologist Dr. Margarita Meehan for treatment of a "longstanding history of migraines," (although the foregoing record is not

consistent with that contention). Ex 4 at 5. Her neurological exam was normal; however, it was observed that dehydration or stress could be headache/migraine triggers. *Id.* Petitioner also underwent a sleep study that August. Ex. 14 at 9. Findings were consistent with moderate daytime somnolence, and she was diagnosed with snoring and idiopathic hypersomnia, and prescribed medication. *Id*. at 29. (Petitioner received follow-up treatment in connection with the sleep study that fall, with the impression being more limited to snoring despite her complaints of symptoms beginning the year before, and it was noted that the medication appeared effective. Ex. 6 at 6, 8; Ex. 14 at 34).

On August 21, 2013, Petitioner was taken to see a different kind of specialist: Peter Procuik, M.D., a naturopathic practitioner. Ex. 12 at 3. In correspondence with Petitioner's mother, Dr. Procuik represented that based on his own experience, Petitioner's symptoms might be associated with the HPV vaccine. *Id*. at 28. Petitioner underwent a sleep study on September 3, 2013, and it produced a diagnosis of Idiopathic Hypersomnia. Ex. 14 at 31. In December 2013, Dr. Procuik more confidently expressed this opinion, stating that "the most likely reason for [A.M.'s] fatigue is an adverse reaction to the gardasil vaccine," and proposing homeopathic treatments in which Ms. McDonald would receive tiny amounts of vaccine in order to stimulate "her own ability to heal the injury caused by the actual vaccine." *Id*. at 26. To that end, Petitioner received a number of homeopathic remedies from August 2013 to October 2014. *Id.* at 12.

In 2014, Petitioner returned to Dr. Wallace, noting that her sleep issues had largely resolved—although she continued to maintain that she had a "history of infectious mononucleosis," and had experienced "extreme fatigue after HPV #3." Ex. 3 at 5, 25. Toward the end of 2014, she saw a different naturopathic physician (Nancy O'Hara, M.D.) for "chronic fatigue from possible vaccine injury." Ex. 2 at 25. The history section of the record from this visit maintained that Petitioner's onset of symptoms had begun in the fall or winter of 2012, although her symptoms worsened after each vaccine dose (meaning onset could have been as early as summer 2012). *Id.* Dr. O'Hara proposed that Petitioner's fatigue could be due to (in part) "impaired mitochondrial/metabolic/glutathione function," leading to "dysregulation of many internal systems" and resulting in chronic fatigue. *Id.* at 27.

Petitioner and her family continued to consult with Dr. O'Hara in early 2015. Lab tests Dr. O'Hara had ordered resulted in Petitioner testing positive for Lyme disease, and in reaction Dr. O'Hara proposed that "mitochondrial and methylation/glutathione dysfunction [was] causing or exacerbating the chronic fatigue." Ex. 2 at 31–32. She also maintained Petitioner likely had an MTHFR mutation[3] reflective of "an underlying folate metabolism and detoxification impairment,"

[3] MTHFR refers to "Methylene Tetrahydrofolate Reductase"—an enzyme involved in folate metabolism—and there is a gene responsible for generation of this enzyme. *See Murphy v. Sec'y of Health & Hum. Servs.*, No. 05-1063V, 2016 WL 3034047, at *5 n.15 (Fed. Cl. Spec. Mstr. Apr. 25, 2016), *mot. for review den'd,* 128 Fed. Cl. 348 (2016). A mutation in the gene can cause failure of the methylation process, which in turn is believed to be related to certain diseases.

while admitting that any association between MTHFR mutations and disease is "still being researched and is not completely defined." *Id.*

To treat the foregoing, Dr. O'Hara prescribed a variety of oral and inhaled supplements. Ex. 2 at 32–34. By April 2015, Petitioner's mother was reporting to Dr. O'Hara that Petitioner was doing better, although it remained Dr. O'Hara's assessment that Ms. McDonald's immune system was likely "still dysregulated with continued evidence of immunodeficiency which of course is impacting her fatigue." Ex. 2 at 35.

## II. Expert Reports

### A. *Abandoned Reports*

Petitioner originally submitted reports from three experts—Drs. Judy Mikovits, Francis Ruscetti, and Karyemaître Aliffe—in addition to a report offered by Dr. Arthur Brawer. *See* Opp. at 3. Those reports proposed a theory that an autoinflammatory reaction to the HPV vaccine was to blame for Petitioner's chronic fatigue. However, prior to the originally-scheduled May 2019 hearing date, the special master to whom the case had previously been assigned ordered the reports stricken, after Petitioner indicated an intent solely to proceed based on the theory advanced by Dr. Brawer (thus requiring that the scheduled hearing be continued, to allow Respondent the opportunity to offer expert testimony in reaction to the newly-articulated causation theory). ECF Nos. 87, 89.[4] Accordingly, since that time Petitioner has limited her causation theory to what Dr. Brawer (supplemented by Dr. Chiodo) has opined.

### B. *Petitioner's Experts*

1. Dr. Arthur Brawer – Dr. Brawer, a rheumatologist, prepared four written reports in this matter. *See* Report, dated January 30, 2019, filed as Ex. 98 (ECF No. 81-2) ("First Brawer Rep."); Report, dated June 5, 2019, filed as Ex. 120 (ECF No. 93-2) ("Second Brawer Rep."); Report, dated May 4, 2020, filed as Ex. 147 (ECF No. 110-1) ("Third Brawer Rep."); Report, dated May 4, 2020, filed as Ex. 148 (ECF No. 110-2) ("Fourth Brawer Rep."). Dr. Brawer has (unlike many Program causation experts) directly examined Ms. McDonald, and opines that she experienced a chronic "Gardasil induced illness" attributable to a toxic reaction brought on by the HPV vaccine.

[4] Petitioner was wise to have abandoned the expert reports of Drs. Ruscetti and Mikovits. I have observed that their opinions lack scientific foundation, and are unreliable and unhelpful in the context of deciding Vaccine Act cases. *See, e.g.*, *McKown v. Sec'y of Health & Hum. Servs.*, No. 15-1451V, 2019 WL 7604714, at *4–5 (Fed. Cl. Spec. Mstr. Dec. 18, 2019) (fees award cutting Dr. Mikovits's fee by 60 percent, and indicating my intent not to entertain opinions from her in future matters).

Dr. Brawer is a rheumatologist in private practice. Brawer Rep. at 1; Curriculum Vitae, dated September 14, 2017, filed as Ex. 100 (ECF No. 81-4) ("Brawer CV"), at 1, 3. Thus, he lacks specific expertise in immunology, toxicology, issues pertaining to the functioning of the autonomic nervous system, or the kind of molecular biology issues that are more often than not raised by vaccine injury cases. He received his M.D. from Boston University, then completed a residency in internal medicine and a fellowship in arthritis. Brawer CV at 3. He has held board certifications in internal medicine and rheumatology (although it is not evident from his CV if they have been maintained over time). *Id.* He has also served as an associate clinical professor at Hahnemann/Drexel University School of Medicine in Philadelphia, as well as an assistant clinical professor of medicine at Robert Wood Johnson University School of Medicine in New Brunswick, New Jersey. *Id.* at 4. He also serves as a diplomate to both the American Board of Internal Medicine and the American Board of Rheumatology. *Id.* at 1, 4. He has also been director of rheumatology at Monmouth Medical Center. *Id.* at 1. He has published a number of articles specific to his expertise (on arthritis) plus relating to the putative toxicity of silicone breast implants (a topic upon which he has offered expert testimony elsewhere). *Id.* at 1–2, 4–8.

*First Report*

Dr. Brawer's initial report was prepared after examining Ms. McDonald in January 2019. In it, he summarized her history, maintaining that her chronic fatigue began within two weeks of her receipt of a first HPV vaccine dose. First Brawer Rep. at 1–2. Since that time (and relying on her own reported history), Dr. Brawer noted, Petitioner had continued to "manifest unremitting, intractable, daily chronicity of her generalized fatigue and other symptomatology." *Id.* at 2. He took note as well of the fact that she had no pre-existing symptoms related to her post-vaccination state, and that to date no medical explanation had been provided for her condition. *Id.* He added that the second and third doses had exacerbated her symptoms while also adding new debilitating features to them. *Id.* at 3.

Despite his embrace of Petitioner's own claims about her health history and status, Dr. Brawer's physical exam of Petitioner revealed nothing out of the ordinary. First Brawer Rep. at 3. And it does not appear from his initial written report that he performed any other tests to ascertain her status or confirm symptoms. He nevertheless proposed that the HPV vaccine doses she had received were causal of her chronic fatigue. *Id.* And in so doing, he attempted to outline a medical theory for how this could have occurred.

First, Dr. Brawer offered an explanation for how the vaccine could have caused a chronic fatigue-like injury. He deemed it "naturally tempting" to offer an "adverse autoimmune reaction" as the likely mediator for the injury at issue, especially since "it is now well known" that many other vaccines are believed to be causal of different autoimmune illnesses in this manner. First

Brawer Rep. at 3. But he acknowledged that a number of reliable studies had negated the assumption that *the HPV vaccine* could similarly instigate an autoimmune process leading to disease. *Id.* at 3–4. He nevertheless maintained the vaccine could be causal, albeit through a different mechanism, based on his contention that the vaccine's "non-antigenic ingredients" (meaning not included for the specific purpose of sparking an immune reaction) could trigger a reaction due to their toxic characteristics. *Id.* at 4. And his contention relied in large part of his view that "HPV vaccine induced illness" is ultimately not simply some autoimmune or easily-understood condition, but instead "an entity unto itself." *Id.* at 6.

Specifically, Dr. Brawer maintained that the HPV vaccine includes polysorbate-80 as a "surfactant and emulsifier."[5] First Brawer Rep. at 4. But the inclusion of this ingredient renders the vaccine cloudy in appearance—requiring in turn the additions of other components like "organosilicones" to clarify the vaccine. *Id.* And silicones, he argued, have "a long and sordid proven history of human toxicity," referencing what was already known about silicone gels used for breast implants. *Id.* Thus, a non-autoimmune toxic reaction to this vaccine ingredient was possible, causing a "multitude of biochemical disruptions," that would in turn promote a chronic condition with persistent symptoms. *Id.* at 4–5. This process could also interfere with energy production by cell mitochondria, triggering immune responses that might appear to be autoimmune in character (even though their etiology was otherwise). *Id.* at 5.

Dr. Brawer's initial report provided little scientific or medical support for his contentions about causality. He maintained that "numerous reports from multiple other countries" had observed similar symptoms after receipt of the HPV vaccine. First Brawer Rep. at 3. Although his report did not cite any such studies specifically as supportive of his theory, the filing of the report was accompanied by the filing of a number of items of literature. *See generally* Exs. 101–15.

Some articles discussed a possible association between the HPV vaccine and autonomic dysfunction broadly, but leaned toward an autoimmune explanation for the association of the sort that Dr. Brawer had both rejected and deemed unrelated to the theory he embraced. *See, e.g.*, S. Blitshteyn et al., *Autonomic Dysfunction and HPV Immunization: An Overview,* Immunologic Research https://doi.org/10.1007/s12026-018-9036-1 (published online on November 27, 2018), filed as Ex. 102 (ECF No. 81-6). Others sought to reveal the mere existence of the HPV-disease association, but with less emphasis on eliding a causal explanation. *See, e.g.*, M. Martinez-Lavin, et al., *HPV Vaccination Syndrome. A Questionnaire-based Study*, 34 Clin. Rheumatol. 1981 (2015), filed as Ex. 109 (ECF No. 82-4); K. Ozawa et al., *Suspected Adverse Effects After Human Papillomavirus Vaccination: A Temporal Relationship Between Vaccine Administration and the Appearance of Symptoms in Japan,* 40 Drug. Saf. 1219 (2017), filed as Ex. 114 (ECF No. 82-9)

[5] "Surface-active Agent," or surfactant, is defined as "a substance that exerts a change on the surface properties of a liquid, especially one that reduces its surface tension, such as a detergent." *Surface-active Agent*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=55175 (last visited Feb. 3, 2023).

("Ozawa"). None expressly referenced or involved the toxicity theory Dr. Brawer offered, however.

Next, Dr. Brawer opined that Ms. McDonald's medical history confirmed that the HPV vaccine was likely causal of her chronic symptoms. She had been symptoms-free pre-vaccination, and no other explanation had been provided for her illness. First Brawer Rep. at 5. And although some testing performed on her had suggested the presence of low platelets (thrombocytopenia) or white blood cells (leucopenia), heavy metals involved in the production of organosiloxanes would likely be explanatory (and those conditions were otherwise associated with "HPV vaccine induced toxicity," although Dr. Brawer offered no support for this sub-contention.

Finally, Dr. Brawer maintained that the temporal relationship between Petitioner's symptoms onset (which he placed at two weeks after receipt of the first dose) and vaccination was medically acceptable. First Brawer Rep. at 5. In support, he referred to a different form of HPV vaccine not administered to Petitioner, Cervarix. *Id.* at 6. That version of the vaccine, he maintained, contains "sodium phosphate dihydrate," the components of which contain "residues of the element silicon in the form of silica (silicon dioxide)." *Id.* This version of the vaccine had also been, he argued, linked to chronic illness—although he did not explain how this rendered the timeframe between receipt of the first HPV dose and Petitioner's onset medically acceptable. Rather, he seemed to determine in conclusory fashion that a two-week timeframe for onset (a timeframe more reliant on witness statements than the actual record) had to be reasonable. *Id.* at 5.

Around the time of the filing of his first report, however, Dr. Brawer also offered a two-page addendum. *See* Report, dated February 5, 2019, filed as Ex. 99 (ECF No. 81-3) ("Brawer Addendum"). He maintained that some points relevant to his causation theory that had been intended to be included in his initial report were "inadvertently omitted" from the report he had just prepared, and therefore he wished to add them now. Brawer Addendum at 1.

In this addendum, Dr. Brawer explained in more detail the scientific basis for his theory. He maintained that vaccines included additives intended to "enhance the humeral and cellular immune response to the antigens in question," and that these additives include "surfactants and emulsifiers" that can produce foaming—a desirable trait for soaps and detergents but not for vaccines. Brawer Addendum at 1. To counteract that possibility, "manufacturers add organosiloxanes"—an ingredient that the Food and Drug Administration (the "FDA") purportedly does not require listed on product labels (based in turn on the conception (false in Dr. Brawer's view) that these substances are inert, and therefore harmless). *Id.*

But these organosiloxanes, Dr. Brawer argued, have the capacity to provoke "inappropriate and unanticipated inflammatory responses," primarily by their interaction with mast cells

responsible for stimulation of inflammation elsewhere. Brawer Addendum at 2. Dr. Brawer did not, however, cite or identify any other literature specific to this causal theory. He also reiterated his prior contention/admission that his theory was independent from the understanding that "autoimmune mechanisms" explained how the HPV vaccine was causal of "HPV vaccine-induced illness." *Id.* at 2.

*Second Report*

The next written report offered by Dr. Brawer is a two-page response to the opinion of Respondent's toxicology expert, Dr. Kendall Wallace (which is discussed below). It begins with (unnecessary) personal criticism of Dr. Wallace, maintaining that he lacks the clinical expertise of rheumatologists who see "legions of patients on the front lines every day" (although why a rheumatologist has the expertise necessary herein to reliably establish that the HPV vaccine can cause a *non-rheumatologic* injury, via a toxic process moreover, is unexplained). Second Brawer Rep. at 1. And Dr. Brawer maintains that Dr. Wallace's response to Dr. Brawer's opinion manifests a "cookie cutter" view of neurological fatiguing syndromes that here deems "untampered by clinical reality." Second Brawer Rep. at 1. Later on, Dr. Brawer accuses Dr. Wallace of "living with his head in the sand" with respect to the viability of the causation theory offered (*Id.* at 2), or that "[v]irtually all biochemists have been brainwashed" into the view that organosiloxanes are inert (and therefore incapable of triggering a toxic reaction (*Id.* at 1).

Moving beyond personal insult, Dr. Brawer made several points in reaction to Dr. Wallace's comments. He denied the general argument that the purported toxicity of silicone-based vaccine ingredients has been rebutted, asserting that "recent events and/or publications in the last ten years" specific to silicone implants causing breast injuries has supported his theory. Second Brawer Rep. at 1. In particular, he noted FDA hearings in 2019 in which numerous complaints of silicone breast implant illnesses were addressed. *Id.* Dr. Wallace, he contended, instead relies on outdated evidence from abroad. *Id.* at 1–2.

Dr. Brawer posited that his own peer-reviewed publications filed in this case establish his general contention of the toxicity of silicone-containing vaccine ingredients. Second Brawer Rep. at 2. But his second report was not accompanied by citation, or the filing of any such items of literature. Rather, he filed only another copy of his CV (upon which he had scribbled a request to former Petitioner's counsel to file certain items). *See generally* Ex. 121 (ECF No. 93-3). However, that same month (and just before the second report was filed), Petitioner had filed two items written by Dr. Brawer.

One article discusses at length the experiences of six women who received silicone gel-filled breast implants. A. Brawer, *Destiny Rides Again: The Reappearance of Silicone Gel-Filled Breast Implant Toxicity,* 26 Lupus 1060 (2017), filed as Ex. 118 (ECF No. 92-2). But this article

says little about Dr. Brawer's scientific, toxicology-based theory about how organosiloxanes could stimulate the kind of symptoms Petitioner alleges—and even less about their introduction into the body via vaccination. The other article he filed at this time was equally unsupportive, and was only a reprint of a *New York Times* article from 2019 setting forth the FDA's intent to review again claims that silicone breast implants could cause injury. Denise Grady and Roni C. Rabin, *Reports of Breast Implant Illnesses Prompt Federal Review,* N.Y. Times, Mar. 19, 2019, at A16, filed as Ex. 119 (ECF No. 92-3).

Dr. Brawer further attempted to undermine Dr. Wallace's contentions that organosiloxanes are not in fact likely even found as an ingredient in the HPV vaccine. Second Brawer Rep. at 2. First, he maintained that there was no FDA or other governmental requirement in the first place to list organosiloxane as a vaccine ingredient (thus implying that its absence as a listed ingredient does not disprove the possibility that it is included). *Id.* Second, he admitted that the HPV vaccine itself does (upon shaking) appear cloudy (and hence undermining his contention that organosiloxane is necessarily included to clarify the solution). *Id.* But he argued that publicly-available photos establish that the clarity of the vaccine is evident *prior* to shaking. *Id.* In the end, he termed it "perfectly logical" to assume that "any solution containing PS-80" would also include some silicone-based substance, like organosiloxanes, to counteract cloudiness or murkiness. *Id.*

*Third Report*

Dr. Brawer's third written report was the first of two dated May 4, 2020, both prepared in response to criticisms leveled at him by both of Respondent's experts. This particular report was in reaction to Dr. Wallace's second report. First, Dr. Brawer highlighted the "plethora of peer reviewed publications" (many of which he noted had been filed in this matter (*see* discussion below)—although Dr. Brawer (again) included no specific cites to these items) that had collectively convinced the FDA to warn against the danger of silicone-containing components in the contest of breast implants. Third Brawer Rep. at 1. Because of such support, he deemed Dr. Wallace's criticisms "misleading and deficient," and in particular took issue with comparing "breast implant illness" to autoimmune connective tissue disorders such as lupus. *Id*. He also maintained that Dr. Wallace had revealed his ignorance of the toxic capabilities of organosiloxanes, reducing overall the reliability of Dr. Wallace's opinion. *Id.* at 2. Otherwise, Dr. Brawer provided no additional substantiation for his opinion.

*Fourth Brawer Report*

The final written report prepared by Dr. Brawer responded to a report from Dr. MacGinnitie, Respondent's immunologist, and it went a bit further than his final response to Dr. Wallace. First, he referenced several items of literature filed in this case (most if not all of which he had authored) as establishing the "hidden toxicity" of HPV components, although only one was

specific to the issues in this case. Fourth Brawer Rep. at 1; A. Brawer, *Hidden Toxicity of Human Papillomavirus Vaccine Ingredients,* 5 J. Rheum. Dis. Treat. 75 (2019), filed as Ex. 143 (ECF No. 99-2) ("Brawer I"); A. Brawer, *Vaccination Induced Diseases and Their Relationship to Neurologic Fatiguing Syndromes, Channelopathies, Breast Implant Illness, and Autoimmunity via Molecular Mimicry,* 4 Int'l. J. Vaccine Immunizat. 1:1 (2020), filed as Ex. 153 (ECF No. 110-7) ("Brawer II").

Second, Dr. Brawer repeated his prior contention that there was no federal regulatory requirement for disclosing the inclusion of organosiloxanes (thus allowing for the possibility that they were in fact part of the HPV vaccine). Fourth Brawer Rep. at 1–2. He also revisited his contention that the FDA was aware of the toxicity of these silicon-containing vaccine components, albeit in the context of breast implants. *Id.* at 2. And he maintained "HPV induced illness" was a substantiated condition, analogizing the preliminary support for it to other conditions that had also once been less understood, like Lyme disease. *Id.* Finally, Dr. Brawer took several opportunities in this report to unreasonably subject Dr. MacGinnitie to the same kind of invective he had directed at Dr. Wallace. *See, e.g.*, Fourth Brawer Rep. at 2 (repeating the criticism that Dr. MacGinnitie had a "cookie cutter" view of immune activation or noting that Dr. MacGinnitie engaged in confusing "ramblings" about post-vaccination autoimmune conditions not bearing on the purportedly-causal toxic process relevant to Dr. Brawer's theory).

*Uncited Literature Filings*

In the midst of offering expert reports, Petitioner filed more than 25 *additional* items of literature purportedly supportive of Dr. Brawer's opinions. *See generally* Exs. 122–42 (filed collectively August 15-16, 2019; Exs. 143–46 (filed September 16, 2019). But the vast majority of these items bear only indirectly on the causation theory offered herein. Many were authored by Dr. Brawer, but are specific to the breast implant context. *See, e.g.*, A. Brawer, *Bones, Groans, and Silicone*, 21 Lupus 1155 (2012), filed as Ex. 122 (ECF No. 96-2) (opinion piece); A. Brawer, *Case Report: Silicone is not Fun in the Sun* 1 Med. Case. Rep. Rev. 3:1 (2018), filed as Ex. 129 (ECF No, 96-9) (detailing woman's development of "multisystem illness" after receiving silicone gel-filled breast implants) ("Brawer Second Case Report"). Others (like prior articles filed) discuss purported impacts of the HPV vaccine, without associating observed symptoms with the mechanism proposed in this case. *See, e.g.*, S. Ikeda et al., *Suspected Adverse Effects After Human Papillomavirus Vaccination: A Temporal Relationship*, 66 Imm. Research 723 (2018), filed as Ex. 132 (ECF No. 97-3) ("Ikeda").

Only a few of the filed articles come anywhere close to being relevant to the theory posited in this matter. One, a case report, was written by Dr. Brawer himself. *See, e.g.*, Brawer I. But Brawer I not only simply reiterates the theory offered herein (without offering reliable research or substantiation for it), but describes the experience of one recipient of the HPV vaccine only,

reporting comparable post-vaccination symptoms with no corroboration they occurred in fact.[6] Another discusses the extent to which organosilicon surfactants in a variety of products might pose toxic risks, using bees in an animal experiment to test. J. Chen et al., *Are Organosilicon Surfactants Safe for Bees or Humans?* 612 Sci. of the Total Environment 415 (2018), filed as Ex. 144 (ECF No. 99-3) ("Chen"). Chen urges the regulation of this additive, but rests this proposal mostly on the toxicity of the ingredient to bees in the context of its use in agriculture or pesticides, and makes no mention of the effects of inclusion in vaccines (let alone whether it even *is* found in vaccines of any kind). Chen at 418–19.

2. Dr. Ernest Chiodo – Dr. Chiodo, a physician and toxicologist, offered the opinion that Ms. McDonald's condition and related symptoms reflected a toxic reaction to the HPV vaccine. *See* Report, dated May 24, 2021, filed as Ex. 166 (ECF No. 124-1) ("Chiodo Rep.").

Dr. Chiodo earned his M.D. at Wayne State University School of Medicine, and also possesses a number of additional degrees, including a Masters in Public Health from Harvard University's School of Public Health, and several masters degrees pertaining to biomedical engineering, occupational and environmental health sciences, and experimental and translational therapeutics. Chiodo Rep. at 1; Curriculum Vitae, filed as Ex. 167 on May 28, 2021 (ECF No. 124-2) ("Chiodo CV"), at 1–2. Although he appears to be licensed to practice medicine, Dr. Chiodo also actively practices health care law as well. Chiodo CV at 3, 4. More than 20 years ago, he served as Medical Director and Manager of Medical and Public Health Services for the City of Detroit, and is a diplomate member of a number of American medical boards. *Id* at 4–5. He has taught at both medical and law schools, and is published on a number of toxic tort-related topics. *Id.* at 6, 28–29.

Dr. Chiodo based his opinion on a review of the record in this case, plus the previously-filed expert reports and associated literature. Chiodo Rep. at 2–3. However, although his report was seven pages in length, substantively-speaking it was fairly thin. First, he summarized Petitioner's history, observing that prior to vaccination she had not experienced anything associated with her post-vaccine symptoms, and that the record revealed no other explanation for her fatigue. *Id.* at 3.

Second, Dr. Chiodo attempted to bulwark Petitioner's theory, albeit by offering an alternative take on causation. Rather than embracing Dr. Brawer's contentions about the undisclosed inclusion of organosiloxanes in the HPV vaccine and their purportedly toxic effects,

[6] Brawer II, by contrast, is a later-filed article that provides an overview explanation for Dr. Brawer's more general contention that "novel and plausible alternative mechanisms" (beyond autoimmune reactions mediated by molecular mimicry) exist to explain "neurologic fatiguing syndromes"—mainly via "organosiloxane-induced" reactions (due to hidden/undisclosed vaccine components). Brawer II at 1, 3. But besides being a review article (and one that relies quite heavily on Dr. Brawer's own publications), Brawer II offers no independent data or evidence to bulwark the reliability of its causal theory.

Dr. Chiodo asserted that the HPV vaccine's adjuvant—"amorphous aluminum hydroxyphosphate"—could *independently* instigate disease. Chiodo Rep. at 4. Based on his own reported review of a National Library of Medicine literature database, Dr. Chiodo maintained that there was reliable evidence that these adjuvants "cause elevated plasma cytokine/chemokine" levels sufficient to instigate a harmful inflammatory response. *Id.* Dr. Chiodo did not cite any independent literature for this contention, but referenced a World Health Organization web page setting forth the HPV vaccine's contents.[7]

Next, Dr. Chiodo considered whether the evidence established that the HPV vaccine "did cause" Ms. McDonald's fatigue. To do so, he invoked the "Reference Manual on Scientific Evidence" (the "Reference Manual")[8] and its standards for evaluating a matter like causation, asserting that the "differential diagnosis process" it describes (by which treaters narrow possible etiologies for a condition) is scientifically reliable (and hence evidentiarily persuasive). Chiodo Rep. at 5–6. Here, he deemed it significant that (a) Petitioner was well pre-vaccination, and (b) no other explanations for her condition, such as a positive Lyme disease infection, had been identified. *Id.* at 6. This fact pattern, he maintained, also was enough to show that the claim requirement that onset occur in a medically-acceptable timeframe was also satisfied—"the new symptoms of Petitioner only occurred after the administration of the HPV vaccine." *Id.*

Dr. Chiodo concluded with criticism of the qualifications of Drs. Wallace and MacGinnitie. Dr. Wallace, he argued, lacked medical expertise, and therefore could not credibly comment on Petitioner's medical history (and the differential diagnosis evidence that he maintained was so probative). Chiodo Rep. at 6. Dr. MacGinnitie, by contrast, lacked toxicology expertise, preventing him from intelligently commenting on the role the vaccine adjuvant could have played herein. *Id.* And neither of Respondent's experts had a background in vaccine manufacture or development, or expertise in public health considerations impacting mass vaccination programs more broadly (in comparison to Dr. Chiodo, who maintained he did have some experience in vaccine development and public vaccine administration). *Id.* at 7. At bottom, Dr. Chiodo deemed their opinions to be *ipse dixit*. *Id.*

C. *Respondent's Experts*

1. Dr. Andrew MacGinnitie – Dr. MacGinnitie, a pediatrician and immunologist, had originally been designated as Respondent's expert in reaction to the expert opinions that Petitioner has abandoned. But he remained an expert for Respondent even after

[7] Dr. Chiodo's report includes a web link purportedly containing the information referenced, but the link is either inaccurate or broken. But Dr. MacGinnitie's Report refers properly to both the officially-published package insert as well as the excipient ingredient list (as discussed below).

[8] *See generally* Fed. Judicial Ctr., *Reference Manual on Scientific Evidence,* at 690 (3d ed. 2011). Dr. Chiodo did not offer the Reference Manual excerpt as a specific exhibit to his report.

Petitioner obtained Dr. Brawer's assistance, and he prepared several reports in response to these additional opinions. *See* Report, dated November 25, 2019, filed as Ex. O (ECF No. 103-1) ("First MacGinnitie Rep."); Report, dated September 22, 2020, filed as Ex. Q (ECF No. 113-2) ("Second MacGinnitie Rep."); Report, dated August 30, 2021, filed as Ex. R (ECF No. 127-1) ("Third MacGinnitie Rep.").

Dr. MacGinnitie is an attending physician and the Clinical Director for the Division of Immunology at Boston Children's Hospital in Boston, Massachusetts. Curriculum Vitae, filed as Ex. B on February 23, 2017 (ECF No. 39-2) ("MacGinnitie CV"), at 1–2. He is also an Associate Professor of Pediatrics at Harvard Medical School. MacGinnitie CV at 1. Dr. MacGinnitie received his undergraduate degree from Yale University, followed by both a medical degree and Ph.D. from the University of Chicago. *Id.* Thereafter, he completed his residency, followed by a fellowship in allergy and immunology at Boston Children's. *Id*. He is board certified in pediatrics and allergy and immunology, and has been in practice as an allergist/immunologist since 2004. *Id*. at 9. Further, he has not only seen patients with various immunologic diseases, including reactions to vaccines, but has published several articles in the area. *Id.* at 11–14.

*First Report*

Dr. MacGinnitie's first report (relevant to the presently-articulated causation theory) contained his reaction to Dr. Brawer's initial report. Although Dr. MacGinnitie acknowledged that he lacked Dr. Wallace's expertise to comment on the purportedly-toxic character of the organosiloxanes allegedly contained in the HPV vaccine, he nevertheless provided his own immunologic-oriented reaction. First MacGinnitie Rep. at 1.

After expressing some confusion as to what Dr. Brawer's causation opinion actually set forth,[9] Dr. MacGinnitie offered his understanding: that silica-containing, non-antigenic substances in the HPV vaccine (included to clarify or stabilize the solution) could trigger a combination of symptoms Dr. Brawer characterized as "Gardasil immunization induced illness." Frist MacGinnitie Rep. at 2. Moreover, Dr. Brawer was not contending that these symptoms were produced by an autoimmune process through the vaccine's stimulation of the immune system itself. *Id.* Dr. MacGinnitie did not, however, find the theory reliable or persuasive.

[9] In particular, Dr. MaGinnitie noted that Dr. Brawer had not cited any independent authority for his assertions in his written report (even if he did later file a variety of items of literature he maintained were supportive of his opinion). First MacGinnitie Rep. at 1–2. This is a valid criticism, as I noted above. Although Petitioner has filed into the record a number of medical or scientific articles to bulwark her claim (and I have reviewed them, consistent with my responsibilities as special master), the fact that Dr. Brawer's reports provide no useful citation to them, let alone discussion of their contents, limits the utility and persuasiveness of his opinion overall.

First (and echoing Dr. Wallace, as explained below), Dr. MacGinnitie expressed doubt that organosiloxanes were an "undeclared excipient"[10] contained in the HPV vaccine, noting that the vaccine's list of ingredients said nothing supporting this supposition. First MacGinnitie Rep. at 2; HPV Vaccine Package Insert, dated April 2015 (http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM111263.pdf) (last accessed Feb. 3, 2023), filed as Ex. O, Tab. 1 (ECF No. 103-2);Vaccine Excipient Summary(https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf) (last accessed Feb. 3, 2023), filed as Ex. O Tab. 2 (ECF No. 103-2) at 2. Moreover, the amounts of these substances (if contained in the vaccine) were overall minimal, and this (plus the fact that the vaccine likely did not provide particularly large amounts of immune stimulation in any event) further reduced the likelihood of an aberrant reaction. First MacGinnitie Rep. at 3.

Second, Dr. MacGinnitie disputed whether there even *was* a cognizable condition that could be characterized as "HPV induced illness." First MacGinnitie Rep. at 3–4. To his knowledge, no official entity (such as the World Health Organization) had identified such an illness, while entities like the American Autonomic Society (the "AAS")) had expressed the consensus of its members that the HPV vaccine was not credibly associated with a variety of dysautonomic conditions comparable to some of the proposed features of HPV vaccine illness. *Id.* at 3, 7; A. Barboi et al., *Human Papillomavirus (HPV) Vaccine and Autonomic Disorders: A Position Statement from the American Autonomic Society*, 223 J. Clinical Autonomic Research 1 (2019), filed as Ex. O, Tab 9 (ECF No. 103-10) (the "AAS Statement"). And Dr. Brawer's references offered to the contrary were deemed "flawed" by Dr. MacGinnitie, who observed that many of them reflected simply the subjective views of individuals who *believed* they had experienced HPV vaccine-related illness, or amounted to case report series articles that displayed selection bias in the individuals discussed or otherwise relied on sweeping and conclusory logic. First MacGinnitie Rep. at 4 (discussing Ozawa).

At the same time, Dr. MacGinnitie noted, there were "sophisticated epidemiologic studies" establishing that the HPV vaccine did not cause the kinds of autoimmune diseases or injuries comparable to the toxic reaction Dr. Brawer proposed. First MacGinnitie Rep. at 5–6; C. Chao et al., *Surveillance of Autoimmune Conditions Following Routine Use of Quadrivalent Human Papillomavirus Vaccine,* 271 J. Intern. Med. 193 (2012), filed as Ex. O, Tab 5 (ECF No. 103-6) (large-scale observational study revealed no increased risk of autoimmune conditions after receipt of HPV vaccine).

Dr. MacGinnitie also called into question the general reliability of the literature offered by Dr. Brawer to support the claim. First MacGinnitie Rep. at 3. Some (including a few items authored by Dr. Brawer) had been published in "predatory" journals that charge fees for publication and are

[10] "Excipient," is defined as "any more or less inert substance added to a prescription in order to confer a suitable consistency or form to the drug; called also vehicle." *Excipient*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=17745&searchterm=excipient (last visited Feb. 3, 2023).

not otherwise subject to valid peer review. *Beall's List of Predatory Journals and Publishers* (2017), http://beallslist.net (last accessed Feb. 3, 2023), filed as Ex. O, Tab. 4 (ECVF No. 103-5). He maintained that seven of Dr. Brawer's offered items had been published in journals identified as predatory (and six were authored or co-authored by Dr. Brawer). First MacGinnitie Rep. at 3 (identifying Exs. 127–130, 135, 143, and 145). Indeed, Dr. MacGinnitie also observed that Dr. Brawer's first expert report (plus the addendum) seemed to have been "recycled" into one of these allegedly predatory journal-published items. *Compare* First Brawer Rep. and Brawer Addendum *with* Brawer I (filed as Ex. 143). Thus, Dr. Brawer was effectively creating (and in a circular manner) an "independent" piece of literature to cite in support of an opinion that *itself* was the source for the secondary article. First MacGinnitie Rep. at 3.

*Second Report*

Dr. MacGinnitie prepared a short supplemental report addressing three of Dr. Brawer's criticisms. First, he disputed Dr. Brawer's claim that organosiloxanes were a likely HPV component, reiterating his prior point that they had never been disclosed to be a vaccine ingredient. Second MacGinnitie Rep. at 1. In response to Dr. Brawer's assertion that there was no formal FDA requirement that the vaccine list the inclusion of organosiloxanes, Dr. MacGinnitie observed that Dr. Brawer supported the contention solely with his own, predatory journal-published articles. *Id.* at 1–2, *citing* Brawer I. (At most, he conceded Dr. Brawer's point that polysorbate-80 was listed as a vaccine excipient, although Dr. Brawer's related point that this ingredient contained organosiloxanes remained speculative). And Dr. MacGinnitie also emphasized the small amounts of silicon which even conceivably might be found in a vaccine (assuming organosiloxanes were found therein), maintaining that he was scientifically qualified to call attention to this fact even if he lacked toxicology expertise. Second MacGinnitie Rep. at 2.

Second, Dr. MacGinnitie rejected Dr. Brawer's argument that in proposing a "black box warning" regarding breast implant dangers, the FDA had likely taken into account the silicone toxicity views of Dr. Brawer's publications. Second MacGinnitie Rep. at 2. Not only had Dr. Brawer offered no proof for this supposition, but it did not rebut Dr. MacGinnitie's fundamental point that predatory journal articles were ultimately unreliable, even if some points they made were reasonable. *Id.*

And third, Dr. MacGinnitie rejected Dr. Brawer's analogy to medical science's incipient understanding of Lyme disease and its causes (which Dr. Brawer had invoked to defend his theory against the fact that "HPV induced illness" is not currently accepted as an actual condition). *Id.* at 2–3. Support for Lyme disease as a cognizable illness, even in the earliest days of its study, was addressed in legitimate and widely-respected medical journals like the *New England Journal of Medicine*. *Id.* at 3. Otherwise, not every "contrarian assertion" about illness is correct, and at

bottom the concept of a specific syndrome or collection of symptoms due to hidden HPV vaccine toxicity was too speculative to accept. *Id.*

*Third Report*

Dr. MacGinnitie's final report offered in this case largely responds to Dr. Chiodo's opinion.[11] Dr. MacGinnitie declined commenting on Dr. Chiodo's challenges to his expertise—although he observed that Dr. Chiodo not only appeared to have never published anything relevant to the causation theory in this case available on a widely-used database, but also that his own report (much like Dr. Brawer's reports) included no supporting literature citations that could be compared to the assertions contained in the report. Third MacGinnitie Rep. at 2.

However, Dr. MacGinnitie disagreed with the reliability of Dr. Chiodo's contention that the HPV vaccine adjuvant (which would encourage elevated cytokines, resulting in a damaging inflammatory response that in turn could induce neurologic harm) could be causal of Petitioner's fatigue and related symptoms. At best, Dr. MacGinnitie allowed, the vaccine "can cause a rise in certain plasma cytokines," but deemed that increase transient, and therefore incapable of causing a subsequently chronic condition. Third MacGinnitie Rep. at 2. Moreover, Dr. Chiodo's theory did not explain how such cytokine upregulation could cause focal inflammation in the CNS sufficient to result in the relevant clinical manifestations, but not elsewhere (and in this case, the medical record did not establish that Ms. McDonald ever displayed any post-vaccination inflammation or "cytokine mediated" symptoms, like fever). *Id.*

Dr. MacGinnitie also questioned the harmful character of the aluminum-based adjuvant used in the HPV vaccine. He noted that this kind of adjuvant had consistently been deemed safe over many years of vaccine inclusion, inducing at most a localized (meaning near to vaccination situs on the arm) inflammation, while actually making the likelihood of an aberrant systemic reaction, or one capable of reaching the central nervous system, less likely. Third MacGinnitie Rep. at 2; H. Hogenesch, *Mechanism of Immunopotentiation and Safety of Aluminum Adjuvants,* 3 Frontiers in Immunol. 406:1 (2013), filed as Ex. R, Tab 3 (ECF No. 128-3), at 9 (review article discussing the generally-recognized safety of aluminum-based vaccine adjuvants, and noting that they actually "reduce the prevalence and severity of systemic adverse reactions"). He further referenced some additional epidemiologic studies that found no association between the HPV vaccine and a condition comparable to Petitioner's complaint, chronic fatigue syndrome. *See, e.g.*, B. Feiring et al., *HPV Vaccination and Risk of Chronic Fatigue Syndrome/Myalgic Encephalomyelitis: A Nationwide Register-Based Study from Norway,* 35 Vaccine 4203 (2017),

[11] Dr. MacGinnitie also briefly reacted to an exhibit authored by Dr. Brawer, but which he maintained had been published in a predatory journal, and which moreover sets forth no studies or data that could be considered as support for its contentions. Third MacGinnitie Rep. at 1. He more generally questioned whether assertions in it specific to the field of rheumatology are helpful in resolving this claim (while conceding otherwise that "rheumatologists are often skilled clinicians with broad-based medical knowledge").

filed as Ex. R, Tab 5 (ECF No, 128-5) ("Feiring") (large cohort study of over 176,000 girls in Norway revealed no increased risk of chronic fatigue after receipt of the HPV vaccine).

2. Kendall Wallace, Ph.D. – Dr. Wallace, a professor of biochemistry and molecular biology with specific expertise in toxicology, prepared four written reports. *See* Report, dated May 24, 2019, filed as Ex. G (ECF No. 91-1) ("First Wallace Rep."); Report, dated November 25, 2019, filed as Ex. M (ECF No. 102-1) ("Second Wallace Rep."); Report, dated August 21, 2020, filed as Ex. P (ECF No. 113-1) ("Third Wallace Rep."); Report, dated August 31, 2021, filed as Ex. S (ECF No. 127-2) ("Fourth Wallace Rep."). Dr. Wallace disputed Petitioner's contention that any non-antigenic components of the HPV vaccine could cause generalized chronic fatigue.

Dr. Wallace is a professor of biochemistry and molecular biology at the University of Minnesota School of Medicine. First Wallace Rep. at 1; Curriculum Vitae, filed as Ex. H on May 28, 2019 (ECF No. 91-2) ("Wallace CV"), at 1. He received a B.S. in Biochemistry from Michigan State University in 1975, followed by an M.S. and Ph.D. in Physiology from the same university. Wallace CV at 1. He has been a professor at the University of Minnesota at Duluth since 1981. *Id.* Prior to joining the Department of Biochemistry and Molecular Biology in 1996, Dr. Wallace was a professor of pharmacology and director of graduate studies for the school's toxicology program, and also director of the school's Chemical Toxicology Research Center. *Id*. Besides teaching, Dr. Wallace conducts laboratory-based research (particularly regarding drug and environmentally-induced mitochondrial toxicity), and has published more than 100 peer-reviewed articles, plus book chapters, and is a reviewer for a number of academic journals. First Wallace Rep. at 1; Wallace CV at 20. Although Dr. Wallace is not a medical doctor, he is board certified in toxicology by the American Board of Toxicology, and is a fellow of the Academy of Toxicological Sciences. *Id*. at 7.

*First Report*

Dr. Wallace's initial opinions in this matter offered reactions to Dr. Brawer's first report. After summarizing Dr. Brawer's theory (in essence, that organosiloxanes contained in the HPV vaccine produce a toxic reaction resulting in chronic fatigue), he addressed in order the medical/scientific literature references offered to support the theory, noting that they not only were not "original research articles," but that they did not otherwise substantiate Petitioner's causation arguments. Several, for example, were merely review articles discussing alleged post-HPV vaccine adverse events, or other kinds of theories not specific to what Dr. Brawer proposed. First Wallace Rep. at 2. Others were specific to vaccine adjuvants only. *Id.* at 3–4 (commenting on Ozawa). Ultimately, Dr. Wallace deemed these items "without relevance to the opinions expressed" by Dr. Brawer. First Wallace Rep. at 4.

By contrast, Dr. Wallace could not independently locate (based on his own research efforts) any reliable, published articles supporting Dr. Brawer's contention that organosiloxanes could prompt an aberrant/toxic response. First Wallace Rep. at 4. And Dr. Brawer had offered no evidence to substantiate the allegation that organosiloxanes were even added to the HPV vaccine (and for the purpose of clarifying the solution) *in the first place*. *Id.* Indeed, HPV vaccine package inserts for both 2006 and 2018 specifically indicated that the vaccine solution would, upon agitation, *become* cloudy—wholly undermining the likelihood that the silica-containing substance was ever added to *prevent* cloudiness. *Id.; see, e.g.*, "Gardasil Highlights of Prescribing Information (Package Insert), dated 2006, filed as Ex. I (ECF No. 91-3), at 12 ("[a]fter thorough agitation, GARDASIL is a white, cloudy liquid"). Organosiloxanes were otherwise not listed as an HPV vaccine ingredient. Ex. I at 12.

Dr. Wallace also more specifically critiqued Dr. Brawer's causation theory on a scientific level. Silicon, he noted was "the second most abundant element in the earth's crust," and "organosiloxanes" are non-volatile, fluid chemical compounds that share a molecular, silica-based motif. First Wallace Rep. at 4–5. Organosiloxanes are used in medical products, food, and food packaging, although humans are most exposed to them via certain food items or cosmetics. *Id.* at 5.

The broad concept of silicon toxicity, Dr. Wallace stated, was a byproduct of reports in the 1980s of silicone breast implant ruptures leading to a variety of medical complaints, including fatigue, nerve pain, or memory issues. First Wallace Rep. at 5. But organosiloxanes have been subject to substantial testing, resulting in "strong scientific consensus that they are of no or minimal risk to human health." *Id* at 5–6. Besides governmental blessing of the safety of organosiloxanes, there were specific animal studies confirming that exposure to organosiloxanes over different temporal periods had no aberrant effects. *Id*. at 6–7. At worst, only direct injection of large amounts of silicon-containing substances could produce an autoimmune or inflammatory response, but none of these studies had determined that silicone *alone* could be harmful in any examined manner. *Id.* at 8. (Dr. Wallace did not, however, file any of the independent evidence he cited in support of these contentions.) Dr. Wallace ultimately rejected the argument that (assuming they were in the HPV vaccine) organosiloxanes could cause any injury at all, let alone the chronic fatigue complained of in this case. First Wallace Rep. at 8.

*Second Report*

Dr. Wallace's next report was a succinct response to Dr. Brawer's somewhat-inflammatory attack on Dr. Wallace's initial report. After vouching for the objective basis for his own opinion and honesty, Dr. Wallace sought to rebut Dr. Brawer's contention that he had failed to consider Dr. Brawer's "multiple peer reviewed publications" on the issue of whether silicone-containing substances could prove toxic. Second Wallace Rep. at 1. Dr. Wallace maintained that his own

literature search had revealed only *three* publications authored by Dr. Brawer—but all were specific to breast implants, as well as distinguishable as an opinion piece or based on a small sample. *Id.* at 1–2. Other publications by Dr. Brawer identified in his CV could not be found in the database searched by Dr. Wallace. Second Wallace Rep. at 2.

In addition, Dr. Wallace took issue with the assertion that the FDA had recently (via public hearings) essentially conceded the legitimacy of claims that silicone breast implants could cause injury (hence allowing for the inference that the same could be true for silicone-containing vaccines). Second Wallace Rep. at 2. Dr. Wallace admitted such a hearing had occurred in 2019, but noted that the hearing's panelists stated that (despite public complaints of post-breast implant complaints of symptoms by members of the public) there was insufficient scientific/medical support to conclude there was any implant-disease association (in particular with "rheumatologic or connective tissue disease diagnosis"). *Id.;* "FDA Executive Summary: Breast Implant Special Topics," FDA Advisory Panel, dated March 25-26, 2019, filed as Ex. N (ECF No. 102-2), at 5. Thus, since the connection between the breast implants and symptoms comparable to what Petitioner complains of in this case had not been established, the comparatively-miniscule amounts of silicone allegedly contained in the HPV vaccine were even less likely to be associated. Second Wallace Rep. at 2 (defining an association as "vanishingly improbable").

*Third Report*

The third written report prepared by Dr. Wallace was a one-page rejoinder to Dr. Brawer's reaction to Dr. Wallace's second report. It largely reiterates the points made in his prior reports. However, the third report also takes issue with the "12 additional publications" Dr. Brawer referenced in his own report as supporting causation. Third Wallace Rep. at 1. These items of literature (like others previously pointed out by Dr. Wallace) all either amount to "anecdotal clinical observations"/case reports specific to breast implants, scientific research not involving silica/silicone toxicity, or Dr. Brawer's own writing on the topic—and while the latter does include an HPV vaccine-oriented article, Dr. Wallace criticized such items as conclusory or as published in questionable, "low impact open source" journals that require a fee for publication. *Id* (referencing Brawer II). In the end, these "authoritative claims of fact" were, in Dr. Wallace's estimation, not only unsubstantiated but "actually distort rather than resolve" what is at issue herein. Third Wallace Rep. at 1.

*Fourth Report*

Dr. Wallace's final written report responds to Dr. Chiodo's report (which as noted above combined a new causal theory, based on vaccine adjuvants, with criticism of Respondent's experts' qualifications). First, Dr. Wallace addressed the alternative theory, noting that it (like Dr. Brawer's) lacked supporting evidence. Dr. Wallace himself attempted to substantiate the concept

that the HPV vaccine could cause harm with his own electronic database literature search, but both studies performed abroad, like Feiring, as well as the AAS statement (the same authorities referenced by Dr. MacGinnitie) rebutted the contention. Fourth Wallace Rep. at 1. One review article went further, addressing but debunking the literature proposing that aluminum-containing adjuvants contained in *any* vaccine could produce injury, while referencing reliable contrary studies. R. Ameratunga et al., *Evidence Refuting the Existence of Autoimmune/Autoinflammatory Syndrome Induced by Adjuvants (ASIA)*, 5 J. Allerg. Clin. Immunol. Pract. 6:1551-5 e1 (2017), filed as Ex. S, Tab 5 (ECF No. 129-5) ("Ameratunga"), at 4 ("the association between vaccination and autoimmunity [due to aluminum-based adjuvants] is likely to be spurious," and "vaccine adjuvant-induced ASIA does not appear to constitute a definable medical condition at this time"). Dr. Wallace also denied knowledge of any publications from the field of toxicology establishing that the small amounts of amorphous aluminum hydroxyphosphate contained in the HPV vaccine could produce injuries comparable to what Petitioner complained of. Fourth Wallace Rep. at 1.

Second, Dr. Wallace questioned whether a differential diagnosis determination by a medical treater was sufficient grounds for a causation finding. Fourth Wallace Rep. at 2. He noted that the medical practice of differential diagnosis "links symptoms, history and test results to disease diagnosis." *Id.* In addition, Dr. Wallace noted that the Reference Manual (which Dr. Chiodo had cited favorably in this regard) expressly distinguished between how differential diagnosis would be employed in medical treatment from its use in a legal setting, thus diminishing the evidentiary value of a treater diagnostic finding when attempting to determine causation as a legal matter—the two could not be conflated such that a treater evaluation *required* a causation finding. *Id.*

Dr. Wallace concluded his commentary on Dr. Chiodo's report by noting that his assertions about the medical acceptability of onset post-vaccination confused a mere temporal association between onset and vaccination with proof of a "temporal concordance"—a concept that Dr. Chiodo had not fully addressed. Fourth Wallace Rep. at 2.

## III. Parties' Arguments

Petitioner's brief in support of her claim provides an abbreviated overview of her relevant medical history. *See generally* Br. at 1–3. She emphasizes the purported onset of her subsequently-chronic fatigue within two weeks of the first vaccine dose in the summer of 2012 (or late June-early July 2012). *Id*. at 1. Records from 2013, she maintains, confirm her fatigue as well as sleep disorder (a condition she had not experienced pre-vaccination). *Id.* at 2–3. By the time of the third dose, she was informing her parents that "she did not feel right in head," and after seeing many treaters was eventually diagnosed with chronic fatigue (and more specifically according to Dr. Brawer, "HPV Vaccine Induced Illness"). *Id.* at 2. Now, she requires coffee and prescribed medications to maintain her alertness during the day. *Id.*

Relying on the above, Petitioner maintains she has met the evidentiary standards for a causation-in-fact claim. First, she argues that she has provided a reliable causation theory associating the HPV vaccine to her "Gardasil"-induced illness. Br. at 3–5. Dr. Brawer contends the HPV vaccine contains several "hidden" chemicals which interact with the immune system sufficient to cause an aberrant process. *Id.* at 3. In particular, organosiloxnanes (known to be toxic from the context of breast implants) are added to the vaccine and trigger a reaction—a contention Petitioner alleges has literature support. *Id.* at 3–4, *citing* Chen and Second Brawer Rep. Respondent's expert, Dr. Wallace, by contrast, lacks foundation in clinical experience or the study of organosiloxanes (unlike Dr. Brawer), and ignores more recent literature on the subject. *Id.* at 4–5.

Second, Petitioner maintains that the record suggests her chronic fatigue/"Gardasil"-induced illness was likely caused by the HPV vaccine series she received, noting that she had none of the alleged symptoms before vaccination, and that there was no other possible explanation in the record for her condition. Br. at 5. And finally, she argues that the timeframe from vaccination to onset was medically acceptable. *Id.* at 6. Based on Dr. Brawer's opinion, Petitioner specifically maintains that her onset began within two weeks of the first vaccine dose—or around June 28, 2012. *Id.* This is consistent with "the time in which it took for Petitioner's body to react to the toxic chemicals." *Id.*

Respondent's brief (four times the length of Petitioner's six-page document) explains the claim's history, noting the aspects of it that have been jettisoned along the way (summarized below in my procedural history of the case). Opp. at 2–7. At the outset, Respondent denies that "Gardasil-immunization induced illness" is a medically-cognizable injury in any regard. *Id.* at 11–15. He notes that Dr. Brawer's conception of the putative condition was addressed by Dr. MacGinnitie but rejected as having no medical diagnostic legitimacy. *Id.* at 12–13. It is at most a *theoretical* disease entity, but lacking the degree of medical acceptance or tested bases to treat as a legitimate medical condition. *Id.* at 15.

Otherwise, Respondent contests whether Petitioner can meet any of her burdens under the causation test enumerated by the Federal Circuit in *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). The "can cause" first *Althen* prong is not met, Respondent argues, because one of its core factual contentions—"that organosiloxanes and/or other chemicals" are found in the HPV vaccine, and in amounts sufficient to instigate a reaction—is unsupported with reliable proof, as Dr. Wallace has shown. Opp. at 16. Moreover, the next step of the theory (in which these toxic elements lead to harm) is equally unsubstantiated, and unpersuasively analogizes what is theorized to occur in the context of breast implants to vaccination. *Id.* at 17–18. Nor are the organosiloxanes themselves definitively understood to be hazardous. *Id.* at 18, 20. Neither Petitioner's literature filings nor case reports preponderantly support her theory, while

reliable large-scale studies confirm that the HPV vaccine does not likely cause the kinds of injuries alleged. *Id.* at 18–19. And Dr. Brawer's expertise has been called into question in other judicial fora, whereas Dr. Wallace is eminently qualified to opine on toxicology matters. *Id.* at 21–22.

The other two *Althen* prongs are also unmet, Respondent contends. Petitioner's second prong showing mainly relies on the temporal association between vaccination and symptoms onset—recognized to be an insufficient basis for entitlement. Opp. at 22–23. By the same token, Dr. Brawer's contention that a two-week onset of fatigue (after receipt of the first HPV vaccine dose) is conclusory, and lacks any provided substantiation for *why* this period of time would be medically-reasonable. *Id.* at 24. As a result, the third, timeframe prong is also unsatisfied. *Id.*

Petitioner reacted to Respondent's brief with a reply comparable in length to her initial brief. *See generally* Reply. She notes that the parties do not seem to dispute that Petitioner experienced chronic fatigue, but rather whether the HPV vaccine could be causal of it. Reply at 2. She reiterates her argument that Dr. Brawer established the toxicity of the alleged additional vaccine components—while highlighting Dr. Chiodo's contentions that there is no other reasonable medical explanation for her symptoms. *Id.* at 2–3. Petitioner only briefly revisits her prong two contentions (emphasizing Petitioner's "progressive worsening" between doses as further bulwarking an association with the vaccine). *Id.* at 3. But she expands on her prong three showing, citing certain literature she filed that suggests that post-HPV vaccine autoimmune reactions would occur within three weeks of the first or second dose, while it could take months for the "definite clinical manifestations." *Id.* at 4. Thus, the initial onset of Petitioner's fatigue and subsequent course was consistent. *Id.* at 4–5.

## IV. Procedural History

This matter was initiated nearly *eight years ago*—an inordinate amount of time for even the most complex of claims (but an especially troublesome fact given where the claim has ended up). The matter was originally assigned to a different special master, and Petitioner was represented by different counsel as well. After the filing of a first round of expert reports (offering a theory different from what is currently maintained), the case was set for trial to be held May 2019 (ECF No. 67). However (and as noted above), Petitioner jettisoned her initial set of experts and proceeded with the current causal theory espoused by Dr. Brawer, causing the hearing to be cancelled so that additional expert input could be obtained. ECF No. 86.

While the second round of expert reports were generated and filed, prior counsel withdrew from the case in April 2020. ECF No. 106. The case was subsequently reassigned to me almost a year later, on March 5, 2021. ECF No. 120. Not long thereafter, and in the midst of final expert filings, I set deadlines for the briefing of a motion for ruling on the record, based on my

determination that the case could reasonably be resolved without a hearing. Briefing was completed in June 2022, and the matter is now ripe for resolution.

## V. Applicable Law

### A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[12] In this case, Petitioner cannot assert a Table claim based on the contention that the HPV vaccine can cause chronic fatigue.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*, 418 F.3d at 1278: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason

[12] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. Appx. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245 ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)).

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *see also LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) ("[h]owever, in the past we have made clear that simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof." (citing *Moberly*, 592 F.3d at 1322)). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored

in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review denied*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. denied* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Legal Standards Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any

diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd sub nom. Rickett v. Sec'y of Health & Hum. Servs.*, 468 F. Appx. 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie*, 2005 WL 6117475, at *20. Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy*, 23 Cl. Ct. at 733 (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

There are, however, situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs.*, 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("'[w]ritten

records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent'") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *Lalonde v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health*

*& Hum. Servs.*, 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339,1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs.*, No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for rev. denied*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. Appx. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

Expert opinions based on unsupported facts may be given relatively little weight. *See Dobrydnev v. Sec'y of Health & Hum. Servs.*, 556 F. Appx. 976, 992–93 (Fed. Cir. 2014) ("[a] doctor's conclusion is only as good as the facts upon which it is based") (citing *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993) ("[w]hen an expert assumes facts that are not supported by a preponderance of the evidence, a finder of fact may properly reject the expert's opinion")). Expert opinions that fail to address or are at odds with contemporaneous medical records may therefore be less persuasive than those which correspond to such records. *See Gerami v. Sec'y of Health & Hum. Servs.*, No. 12-442V, 2013 WL 5998109, at *4 (Fed. Cl. Spec. Mstr. Oct. 11, 2013), *aff'd*, 127 Fed. Cl. 299 (2014).

D. *Consideration of Medical Literature*

Both parties filed medical and scientific literature in this case, but not every filed item factors into the outcome of this decision. While I have reviewed all the medical literature submitted

in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.,* 527 F. Appx. 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

E. *Determining Matter on Record Rather Than at Hearing*

I have opted to decide this case based on written submissions and evidentiary filings, including the numerous expert reports that have been submitted. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions (or components of a claim) on the papers rather than via evidentiary hearing, where (in the exercise of their discretion) they conclude that the former means of adjudication will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The Federal Circuit has recently affirmed this practice. *Kreizenbeck v. Sec'y of Health & Hum. Servs.*, 945 F.3d 1362, 1365–66 (Fed. Cir. 2020). It simply is not the case that every Vaccine Act claim need be resolved by hearing—even where the petitioner explicitly so requests.

## ANALYSIS

### I. HPV Vaccine-Based Claims are Largely Unsuccessful

I begin by noting that claims the HPV vaccine can cause nonspecific symptoms like fatigue, or more specific interference with the autonomic nervous system sufficient to trigger autonomic dysfunction manifesting in a variety of ways (from tachycardia, to generalized orthostatic intolerance, to postural orthostatic tachycardia syndrome ("POTS")), have routinely been dismissed. *See e.g.*, *America v. Sec'y of Health & Hum. Servs.*, No. 17-542V, 2022 WL 278151, at *27 (Fed. Cl. Spec. Mstr. Jan. 4, 2022) (neurocardiogenic syncope); *Hughes v. Sec'y of Health & Hum. Servs.*, No. 16-930V, 2021 WL 839092 (Fed. Cl. Spec. Mstr. Jan. 4, 2021) (complex regional pain syndrome ("CRPS") and/or POTS), *mot. for review den'd,* 154 Fed. Cl. 640 (2021); *E.S. v. Sec'y of Health & Hum. Servs.*, No. 17-480V, 2020 WL 9076620, at *42 (Fed. Cl. Spec. Mstr. Nov. 13, 2020) (small fiber neuropathy), *mot. for review den'd*, 154 Fed. Cl. 149 (2021); *McKown v. Sec'y of Health & Hum. Servs.*, No. 15-1451V, 2019 WL 4072113 (Fed. Cl. Spec. Mstr. July 15, 2019) (POTS and eczema); *Johnson v. Sec'y of Health & Hum. Servs.*, No. 14-254V, 2018 WL 2051760 (Fed. Cl. Spec. Mstr. Mar. 23, 2018) (POTS and fatigue); *Combs v. Sec'y of Health & Hum. Servs.*, No. 14-878V, 2018 WL 1581672 (Fed. Cl. Spec. Mstr. Feb. 15, 2018) (vasovagal syncope); *see also Otto v. Sec'y of Health & Hum. Servs.*, No. 16-1144V, 2020

WL 4719285 (Fed. Cl. Spec. Mstr. June 17, 2020) (case involving HPV vaccine dismissed after hearing at claimant's request).

It just so happens that I have decided many of these cases myself (several after a trial as well), giving me some background in understanding the science and reasoning behind this kind of claim. Although these prior determinations do not bind the outcome herein (and admittedly the theory that the HPV vaccine contains undisclosed toxic ingredients was not squarely at issue in these numerous prior cases), I need not pretend that the present case is overall unique, or bury my head in the sand and disregard how similar matters have been resolved in the past. I also reference these prior determinations because much of the literature offered herein to show the HPV vaccine can be associated with fatigue or various forms of dysautonomia have been deemed unreliable or unpersuasive. *See, e.g.*, *Hughes,* 2021 WL 839092, at *14, 31, and 33, and *Johnson,* 2018 WL 2051760, at *8, 12, and 24 (discussing weaknesses of Ozawa); *E.S.,* 2020 WL 9076620, at *14, 44 (discussing Ikeda). In short, a claimant seeking to prove the HPV vaccine causes generalized and otherwise non-specific kinds of symptoms has a steep hill to climb.

## II. Petitioner Has Not Preponderantly Established a Cognizable Vaccine Injury

Numerous Program cases note that claimants must establish some kind of recognized injury, rather than simply list deleterious symptoms occurring in a post-vaccination timeframe. *Broekelschen*, 618 F.3d at 1346, 1349. It is thus often necessary at the outset of analyzing a petition to determine whether a given alleged injury has been preponderantly established in the first place. *Locane v. Sec'y of Health & Hum. Servs.,* 685 F.3d 1375, 1381 n.3 (Fed. Cir. 2012); *Lombardi v. Sec'y of Health & Hum. Servs.,* 656 F.3d 1343, 1353 (Fed. Cir. 2011).

This poses a threshold deficiency with this case—for the medical record does not preponderantly establish that Ms. McDonald has experienced an unusual degree of fatigue. Indeed, there is little objective proof of fatigue in the months after her initial receipt of the HPV vaccine doses, with no real concrete medical confirmation of this kind of problem before January 2013.[13] In addition, Petitioner's experts have not at all established that the medical community recognizes the existence of *any* kind of HPV vaccine/"Gardasil" injury featuring persistent and debilitating fatigue comparable to what is alleged. For purposes of analysis, however, I will assume that Petitioner's medical history *does* establish unusually-chronic fatigue, in order to evaluate whether Petitioner has demonstrated "more likely than not" that the HPV vaccine was responsible for her alleged condition.

[13] There is some reliable record support for a hypersomnia diagnosis, based on a sleep test Petitioner underwent in September 2013. *See generally* Ex 14 at 29, 31. But this occurred too long after vaccination to credibly associate it with the HPV vaccine, especially given the paucity of consistent evidence of chronic fatigue from the alleged onset time in the summer of 2012, and treaters who gave this test result weight in associating the vaccine with Petitioner's fatigue arrived at their opinion in a conclusory manner, without any discussion of how vaccination *led* to this condition.

## II. Petitioner Has Not Carried Her Burden of Demonstrating Causation Based on the Three *Althen* Prongs

Analysis of a claimant's success in meeting the *Althen* prongs relevant to causation often requires careful review of each prong individually, with discussion of the evidence offered on each element pro and con, in order to demonstrate how various items of evidence were weighed. In particular, special masters frequently must delve deeply into the filed expert reports and literature—both to ensure they understand the causation theory offered, and also to weigh whether the individual items of evidence relied upon are worthy of being deemed probative.

Not here. Petitioner's inability to meet her burden of proof with preponderant showings on *any* of the causation prongs is fairly self-evident, and can be discerned without the kind of in-depth evaluation that other cases demand. The demands of the Program's ever-burgeoning docket obligate special masters to make wise use of their time, and in so doing focus less attention on claims that are more obviously deficient, reserving their attentions for complex or fact-heavy cases in which more reliable and evidentiarily-supported claims are advanced. Hence, I will only roughly sketch the significant deficiencies of Petitioner's overall showing.[14]

First, Petitioner cannot demonstrate that the HPV vaccine can produce a toxic reaction comparable to the (alleged) reaction[15] induced by silicone-containing breast implants. In fact, there is no reliable proof to establish that organosiloxanes are even *included* in the HPV vaccine, with Dr. Brawer relying on a combined "can't prove a negative" argument that nothing *disproves* they are *not* included, plus the contention that they are needed to prevent cloudiness (even though the vaccine's own package insert discloses that cloudiness *occurs* with the vaccine). Dr. Brawer also did not establish with reliable proof (beyond his own *ipse dixit* assertions) that the amounts of these substances—*if* they could be shown to be found in the vaccine—would be sufficient to spark a toxic reaction. *How* the silicone substances would do this is wholly unsupported by independent proof—no studies or reliable scientific/medical articles establish any risk of chronic fatigue from the inclusion of these substances in a vaccine. Ultimately, Dr. Brawer relied too much on commentary and articles he had written (which, as Respondent's experts pointed out, had questionable legitimacy as independent, reliable items published in accordance with peer-reviewed

[14] Notably, another special master (when confronted with a similar combination of expert opinions from Drs. Brawer and Chiodo regarding the toxicity of silicone-based "secret" HPV vaccine components) acted more expeditiously (via a Rule 5 conference, while the case was pending but well before hearing) to point out the case's glaring deficiencies, and went so far as to question the claim's reasonable basis. *See Brunker v. Sec'y of Health & Hum. Servs.,* No. 18-683V, 2023 WL 21255, at *3–6 (Fed. Cl. Spec. Mstr. Nov. 29, 2022) (reducing awarded fees and costs after claim's voluntary dismissal). In doing so, the special master noted not only that the expert opinions and other evidence had substantial deficiencies, but also that (as here) Dr. Chiodo's expert theory was inexplicably inconsistent with Dr. Brawer's. *Brunker,* 2023 WL 21255, at *5–6.

[15] Dr. Brawer certainly did not establish that breast implants *themselves* are toxic, but I will assume for sake of discussion that he offered preponderant proof to that end.

practices) to prove his points, rather than on facially-reliable research or study results. It is far from evident that Dr. Brawer, a rheumatologist, even possesses the expertise to offer the opinion he has. And his combative approach in reacting to Respondent's experts with unnecessary derogatory comment only served to diminish his credibility and persuasiveness.

Dr. Chiodo's alternative theory was no more successful. His theory is inconsistent with Dr. Brawer's opinion, who not only proposes a non-autoimmune-mediated reaction due to an unidentified vaccine ingredient, but seemed to agree in his reports that the latter explanation for causation in the context of the HPV vaccine had been successfully *rebutted* by science. *See* First Brawer Rep. at 3–4 (noting that "recent publications" as of 2018 had "negated most if not all" associations between the HPV vaccine and adverse autoimmune-mediated reactions). More so, Dr. Chiodo's opinion about the role adjuvants might play in triggering an autoimmune response perilously borders the discredited "ASIA" theory (which contends that aluminum included as an adjuvant in vaccines can trigger a variety of autoimmune illnesses). Ameratunga; *see also Monzon v. Sec'y of Health & Hum. Servs.*, No. 17-1055V, 2021 WL 2711289, at *8 n.6 (Fed. Cl. Spec. Mstr. June 2, 2021) ("[t]he ASIA theory for adjuvant-induced autoimmunity has never been deemed medically reliable in any prior Program cases." (citations omitted)). Otherwise, Dr. Chiodo's opinion is even less well-substantiated than what Dr. Brawer offered. And Dr. Chiodo devoted time in his report to discussing the proper standard for evaluating causation in Program cases—despite the fact that Program experts are not called upon to offer opinions on legal questions, but should instead provide opinions based on medical or scientific expertise only.

This matter underscores the difference between a "plausible" theory (here, barely so) and one that has reliable scientific/medical support—and more importantly, why the *latter* is the proper standard for evaluating whether a claimant has met her *Althen* prong one burden. It is not beyond the realm of possibility that the same substance that could arguably be toxic in one medical context (when included as a breast implant ingredient) could in a different context (vaccination) have a comparable impact. But to reach the level of *preponderance,* a claimant would need to offer reliable items of literature specific to vaccination, or otherwise showing that an extremely small amount of silicon-containing ingredients (in comparison to the amounts in a breast implant) could cause an injury comparable to what is alleged in this case. The claimant might also opt to identify experts who had demonstrated research knowledge of the issue and utilize their services in "connecting the dots" despite the absence of more direct proof (a more than permissible strategy in Vaccine Act cases). A successful *Althen* prong one showing may begin with only a plausible theory, but that theory must then be fleshed out with reliable scientific and medical evidence if it is to rise above interesting speculation.

But the proposed theories Petitioner's experts offered were almost *wholly without* such support, given not only the paucity of evidence establishing that the organosiloxanes *could* cause long-term fatigue, but *the very absence of proof they are even contained in the vaccine in the first*

*place*. It simply has not been demonstrated that "more likely than not" the HPV vaccine can cause chronic fatigue due to undisclosed ingredients comparable to substances contained in silicone breast implants.

Second, the remaining two *Althen* prongs were also unsupported with sufficient reliable and persuasive proof. I cannot possibly conclude, for example, that the HPV vaccine Petitioner received *did* likely cause her subsequent fatigue. Nothing from the medical record corroborates the alleged toxic reaction until long after the HPV dosage course was completed, and although some later treaters suggested the vaccine was causal, I discount their views (either because they were practitioners of alternative medicine unqualified to offer a credible causation opinion, or because their causality assessment was provided too long after Petitioner's vaccinations and purported onset). The medical record does not even confirm symptoms in the six months or so from Petitioner's first dose of the HPV vaccine, while showing times later when Petitioner did not actively report issues. It has also not been shown that the version of the HPV vaccine she received *did* contain organosiloxanes, and without that finding, the fact that this ingredient "could cause" an injury is meaningless.

Petitioner also did not establish that her symptoms began in a medically-reasonable timeframe after vaccination. The record does not demonstrate or corroborate symptoms in the fall of 2012, after the first HPV dose, and no reliable explanation has been provided for why months would pass between the second and third doses before Petitioner would begin to complain of symptoms (in January 2013). And Dr. Brawer did not provide a persuasive explanation for how the two vaccine doses might interact, or why the first would produce no concerning symptoms (while the second would initially prompt slightly different symptoms than the fatigue that Petitioner ultimately asserts she experienced). He also did no more than maintain that the acceptability of the timeframe from vaccination to onset (allegedly two weeks after the first dose) arose from the *literal* temporal relationship between vaccination and when Petitioner began to complain of fatigue, without showing what about the toxicity of the undisclosed vaccine ingredient would cause her fatigue to progress as it did. At most, Petitioner relies on her symptoms beginning "after" vaccination—an insufficient basis for finding the third *Althen* prong has been met.

## III. This Matter Was Appropriately Resolved Without a Hearing

In ruling on the record, I am choosing not to hold a hearing—contrary to Petitioner's request. Determining how best to resolve a case is a matter that lies generally within my discretion, but I shall nevertheless explain why a hearing was not required.

Prior decisions have recognized that a special master's discretion in deciding whether to conduct an evidentiary hearing "is tempered by Vaccine Rule 3(b)," or the duty to "afford[] each party a full and fair opportunity to present its case." *Hovey v. Sec'y of Dep't of Health & Hum.*

*Servs.*, 38 Fed. Cl. 397, 400–01 (1997) (citing Rule 3(b)). But that rule also includes the obligation of creation of a record "sufficient to allow review of the special master's decision." *Id*. And such a record *can* be created based solely on the filings in the case (which are more often than not voluminous, including medical record documents, expert reports, and attorney brief filings). Accordingly, the fact that a claim is legitimately disputed, such that the special master must exercise his intellectual faculties in order to resolve disputes of fact or law, is not *itself* grounds for a trial (for if it were, trials would be required in every disputed case). Special masters are expressly empowered to resolve fact disputes without a hearing—so long as a party has been given the proper "full and fair" chance to prove their claim.

The present claim could be, and was, resolved fairly without live testimony from the experts. The case turns almost exclusively on whether the HPV vaccine can cause chronic fatigue—and as noted, I have familiarity with HPV vaccine-oriented claims. Moreover, Petitioner's showing was ineffective—a conclusion that I can reach simply on the basis of the written submissions, record, and expert reports filed. Indeed, although I did not manage the case for the entirety of its life, and although I do not decide this matter on the basis of anything other than the theory ultimately offered, Petitioner's willingness to jettison theories, and experts, during its course underscores the extent to which the claim was futilely in search of a persuasive theory. The theory ultimately landed upon was simply too thin and unpersuasive—a determination I would surely have reached even had I heard testimony from Petitioner's experts.

## CONCLUSION

Petitioner has not preponderantly established that the HPV vaccine doses she received can cause "Gardasil illness," or did so to her, in the manner her experts have opined. Accordingly, she is not entitled to damages, and her claim warrants dismissal. In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk of Court shall enter judgment in accord with this Decision.[16]

**IT IS SO ORDERED.**

s/ Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[16] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.